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10/783,783	02/20/2004	Alan R. Klenk	MVMDINC.060A	6668

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KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
YABUT, DIANE D	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
10/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcarter@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/783,783

Applicant(s)

KLENK ET AL

Examiner

Diane Yabut

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received 08 June 2007.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1 and 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**).

Claims 1 and 10: Gifford discloses delivering an elongate body **204** having a proximal end and a distal end to the patent foramen ovale, the elongate body having a tissue piercing structure at its distal end and a coil **200** releasably engaged with the elongate body, advancing the tissue piercing structure and the coil through the septa **SP**, **SS** of

the patent foramen ovale, wherein both the tissue piercing structure and the coil extend into the septum primum and the setptum secundum, and releasing the coil from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale, wherein the coil when released contracts to pinch the septum primum ("sp") and septum secundum ("ss") together (Figures 23A-23B, page 10, paragraph 98).

Claim 9: Gifford discloses the elongate body being delivered through an outer catheter **202** (Figures 23A-23B).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) in view of **Pierson, III ("Pierson")** (U.S. Patent No. **6,663,633**).

Claim 2: Gifford discloses the claimed invention except for the elongate body having an opening near its distal end.

Pierson teaches an elongate body **40** having an opening near its distal end (Figure 1A). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an elongate body having an opening near its distal end, as taught by Pierson, to Gifford since it was known in the art an opening would allow the coil

element to effectively engage with the elongate body without the use of a separate fastening or attachment device.

Claim 11: Gifford discloses the claimed device, including the coil being a first coil and releasing the first coil from the elongate body (see Claims 1 and 10 in paragraph 2 above), except for withdrawing the tissue piercing structure from the septa of the patent foramen ovale, advancing the tissue piercing structure and a second coil releasably engaged with the elongate body through the septa of the patent foramen ovale at a location adjacent to the first coil and releasing the second coil from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale, wherein the second coil when released contracts to pinch the *sp* and the *ss* together. In other words, Gifford essentially discloses the claimed device except for withdrawing the tissue piercing structure from the septa and using a second coil adjacent to the first coil to draw the septa together.

Pierson teaches a first coil **12** and an adjacent second coil **12'** that draw the two ends of the tissue **90** together and withdrawing the tissue piercing structure **40** from the septa (Figures 1A-1E). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second coil to the septa of the patent foramen ovale, as taught by Pierson, to Gifford in order to provide a more secure closure of the *sp* and the *ss* by covering more surface area of the tissue.

Claims 12-19: Gifford discloses the claimed invention, including closing a patent foramen ovale having an *sp* and *ss* and advancing and releasably engaging a coil over a single elevery device or elongate body at a location proximate the patent foramen

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ovale and least partially through the septa of the patent foramen ovale using a tissue piercing structure on the distal end of the elongate body to secure the *sp* and *ss* together, including advancing the coil first through either of the *sp* or *ss* and then through the other septum (see explanation for Claims 1 and 10 above), except for using a plurality of coils, or three coils, advanced sequentially through a single catheter.

Pierson teaches advancing a plurality of coils **12** and **12'** to draw opposing sides of tissue **90** together through a single catheter (Figures 1A-1E and col. 7, lines 61-67, col. 8, lines 1-17). See discussion of Claim 11 above that recites this limitation using Pierson. It would have been obvious to one of ordinary skill in the art to provide the advancement of a plurality of coils through a single catheter, as taught by Pierson, to Gifford in order to facilitate the subsequent advancement of the second coil after the first coil without having to reload or use another device. It also would have been obvious to one of ordinary skill in the art to provide three coils to Gifford since it was known in the art that the use of multiple fasteners covers more surface area and strengthens the binding force and closure of tissue.

5. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Pierson, III ("Pierson")** (U.S. Patent No. **6,663,633**), as applied to Claim 2 above, and further in view of **Johnson** (U.S. Pat. No. **6,485,504**).

Claims 3 and 4: Gifford and Pierson disclose the claimed invention, including the coil being advanced through the patent foramen ovale, except for the coil having a distal

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end that releasably engages the opening in the elongate body near its distal end and a loading portion that releasably engages a proximal end of the coil, the coil being advanced while being engaged with both the loading portion and the opening near the distal end of the elongate body to axially elongate and radially reduce the coil.

Johnson teaches a coil **100** with a distal end that releasably engages the opening **116** in the elongate body **108** near its distal end and a loading portion (the proximal end of **108**) that releasably engages a proximal end of the coil, the coil being advanced while being engaged with both the loading portion and the opening near the distal end of the elongate body to axially elongate and radially reduce the coil, in order for the coil to fit into the hole in the tissue (Figures 24-26 and col. 19, lines 9-32). It would have been obvious to one of ordinary skill in the art to provide a coil that is releasably engaged at both proximal and distal ends to a loading portion and an opening in the distal end of the elongate body, respectively, to axially elongate and radially reduce the coil, as taught by Johnson, to the combined device of Gifford and Pierson in order to effectively narrow the coil in diameter to fit the hole in the tissue.

6. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**), as applied to Claim 1 above, and further in view of **Laufer** (U.S. Pub. No. **20040193194**).

Claims 5-7: Gifford discloses the claimed device, including delivering an elongate body to the patent foramen ovale, except for delivering a loading collar with the elongate

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body, the loading collar releasably engaging a proximal end of the coil, the elongate body configured to be rotatable and axially slideable relative to the loading collar.

Laufer teaches delivering a loading collar **864** with the elongate body **881a** or **881b**, the loading collar releasably engaging a proximal end of the coil, the elongate body configured to be rotatable and axially slideable relative to the loading collar. (Figures 14A-14B and page 6, paragraphs 114-115). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading collar with the elongate body that is releasably engaged to the proximal end of the coil, as taught by Laufer, to Gifford in order to protect and secure the proximal end of the coil and advance it towards the tissue while avoiding the need for another instrument to release the coil from the proximal end into the tissue.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Laufer** (U.S. Pub. No. **20040193194**), as applied to Claim 7 above, and further in view of **Johnson** (U.S. Pat. No. **6,485,504**).

Claim 8: Gifford and Laufer disclose the claimed device except for the elongate body being advanced relative to the loading collar prior to advancing the coil to axially elongate the coil. See paragraph 5 above for discussion of Claims 3 and 4 that recite this limitation using Johnson.

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8. Claims 20-21, 26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) in view of **Kobayashi** (U.S. Pat. No. **6,375,671**).

Claims 20-21 and 26: Gifford discloses the claimed device, including a loading portion **204** adapted to releasably engage a distal end of a coil **200** and a distal structure (distal end of coil **200**) adapted to releasably engage a distal end of the coil **200** using a tissue piercing structure that is integral with the tissue piercing structure for extending through a septum primum and septum secundum of a patent foramen ovale (see Claims 1 and 10 in paragraph 2 above), except for the loading portion adapted to releasably engage a proximal end of the coil and the loading portion holding the coil relative to the piercing structure to axially elongate and radially reduce the coil.

Kobayashi teaches a loading portion **4** adapted to releasably engage a proximal end of a coil **1** and the loading portion holding the coil relative to the piercing structure to axially elongate and radially reduce the coil (Figures 5-8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading portion that releasably engages a proximal end of a coil, as taught by Kobayashi, to Gifford in order to effectively narrow the coil in diameter to fit the hole in the tissue.

9. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Kobayashi** (U.S. Pat. No. **6,375,671**), as applied to Claim 21 above, and in further view of **Kay** (U.S. Patent No. **5,662,683**).

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Claim 22: Gifford and Kobayashi disclose the claimed device except for the loading portion comprising a slot adapted to receive the proximal end of the coil.

Kay teaches a loading portion **30** comprising a slot **44** adapted to receive the proximal end of the coil **10**, which enables the surgeon to apply a force to the coil (Figure 7, col. 4, lines 49-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading portion comprising a slot, as taught by Kay, to Gifford and Kobayashi in order for the surgeon to apply a force to the coil, which facilitates its delivery to tissue.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**), **Kobayashi** (U.S. Pat. No. **6,375,671**), and **Kay** (U.S. Patent No. **5,662,683**) as applied to Claim 22 above, and further in view of **Pierson, III ("Pierson")** (U.S. Patent No. **6,663,633**).

Claim 23: Gifford, Kobayashi, and Kay disclose the claimed device except for the tissue piercing structure having an opening adapted to releasably engage the distal end of the coil. See Claim 2 above in paragraph 4 that recites this limitation using Pierson.

11. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Kobayashi** (U.S. Pat. No. **6,375,671**), as applied to Claim 20 above, and further in view of **Laufer** (U.S. Pub. No. **20040193194**).

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Claims 24 and 25: Gifford and Kobayashi disclose the claimed device except for a loading collar, and the tissue piercing device being moveable relative to the loading collar, and the tissue piercing structure being provided on an elongate body extending through the loading collar.

Laufer discloses a loading collar **864** with the tissue piercing structure **881b** provided on an elongate body having a proximal end and a distal end, the elongate body extending through the loading collar (Figure 14B and page 6, paragraph 114). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading collar, as taught by Laufer, to Gifford and Kobayashi since it was known in the art that loading collars abut against the tissue to stabilize the surgical site and facilitate deployment of devices that engage with the tissue.

12. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Kobayashi** (U.S. Pat. No. **6,375,671**), as applied to Claim 26 above, and further in view of **Bolduc** (U.S. Patent No. **5,582,616**).

Claims 27-28: Gifford and Kobayashi disclose the claimed device except for the proximal and distal end of the coil comprising a tang that extends into a diameter defined by the coil.

Bolduc teaches a proximal end of a coil **110** comprising a tang **122** that extends into a diameter defined by a coil in order to connect it to a delivery mechanism (Figure 3). Although Bolduc does not disclose a similar tang on the distal end of the coil

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(Gifford does disclose a distal tang **201** in Figure 23A, although used as a barb), it would have been obvious to one of ordinary skill in the art to provide a tang on either or both ends of the coil to Gifford and Kobayashi in order to attach the coil to a delivery device so that it can be effectively secured before being attached to a tissue.

13. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Kobayashi** (U.S. Pat. No. **6,375,671**), as applied to Claim 20 above, and further in view of **Pierson, III ("Pierson")** (U.S. Pat. No. **6,663,633**).

Claim 30: Gifford and Kobayashi disclose the claimed device except for the loading portion being adapted to releasably engage a plurality of coils.

Pierson teaches a loading portion **10** being adapted to releasably engage a plurality of coils (Figures 1A-1E and col. 7, lines 61-67, col. 8, lines 1-17).

See Claims 12-19 above in paragraph 4 that recite this limitation using Pierson.

Response to Arguments

14. Applicant's arguments filed 18 June 2007 have been fully considered but they are not persuasive.

15. Applicant generally argues that nowhere does Gifford disclose that part of the elongate member pierces, enters, or comes into contact with tissue. The examiner asserts that barb **201** can be considered as the tissue piercing structure, which is attached to the elongate body and is positioned at its distal end when it advances the

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coil into the septa (Figures 23A-23B), as recited in Claim 1, and therefore this reads on the claim limitation.

16. Applicant also argues that one skilled in the art would not look to Pierson to modify a PFO method as in Gifford, and that it is unclear as to what the opening of the elongate body is (as recited in Claim 2) in Pierson. The examiner asserts that Pierson teaches delivering helical or coil elements to fixate or approximate tissue, and therefore it is reasonable to assume that one skilled in the art would modify Gifford with teachings in Pierson. The examiner considers the opening to be apparent in Figure 1A, where the distal end of coil **20** extends through a hole or opening in the delivery member **40**, and it would have been obvious to one of ordinary skill in art to modify Gifford with this feature since it allows secure and effective engagement of the coil with the delivery member which avoids undesirable or inadvertent disengagement or deployment of the coil into tissue.

17. Applicant argues that Gifford does not teach or suggest releasably engaging a plurality of coils with a single delivery device, advancing the single delivery device carrying the plurality of coils into a patient to a location proximate the patent foramen ovale, and that Kobayashi does not disclose any tissue piercing structures. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. Gifford is meant to be combined with Pierson and Kobayashi.

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18. Applicant also generally argues that one would not look to Kobayashi to combine with Gifford, since Kobayashi does not refer to a PFO, but rather a flap and patent channel. However, Kobayashi teaches a closure device and method using a helical or coil element, and therefore it is reasonable to assume that one skilled in the art would modify Gifford with teachings in Kobayashi. The examiner focuses on modifying Gifford with the specific teaching of Kobayashi that involves releasably engaging a proximal end of the coil with the delivery device, which would have been obvious to one of ordinary skill in art since it would allow the surgeon to manipulate or control the coil the surgeon, which facilitates careful delivery into tissue, and therefore the combination is proper.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER